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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,701	01/05/2001	Allan S. Hoffman	UWOTL119001	3998
26389	7590	12/20/2005	EXAMINER	
CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC			TRAN, MY CHAU T	
1420 FIFTH AVENUE			ART UNIT	
SUITE 2800			PAPER NUMBER	
SEATTLE, WA 98101-2347			1639	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/755,701	Applicant(s) HOFFMAN ET AL.	
	Examiner MY-CHAU T. TRAN	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4,8,9,13-17,19,33-36 and 38-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-44 is/are allowed.
- 6) ☒ Claim(s) 2-4,8,9,13-17,19 and 33-36 is/are rejected.
- 7) ☒ Claim(s) 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application and Claims Status

1. Applicant's amendment and response filed 10/19/2005 is acknowledged and entered. Claims 33, 38 and 41 have been amended.
2. The amendment filed on 02/08/2005: cancelled claims 6, 18, and 20-32; amended claims 2-4, 8, 13, 17, 19, 33, and 34; and added claims 38-44.
3. The amendment filed on 02/18/2004: cancelled claims 11 and 37; and amended claims 3, 8, and 13.
4. The amendment filed on 06/24/2003: cancelled claims 1, 5, 7, and 12; amended claims 2-4, 6, 8-11, and 13-19; and added claims 33-37.
5. Claims 2-4, 8, 9, 13-17, 19, 33-36, and 38-44 are pending.

Election/Restrictions

6. The instant species election requirement is still in effect as there is no allowable generic or linking claim. Applicant has elected with traverse the following species for the elected invention (Claims 2-4, 8, 9, 13-17, 19, 33-36, and 38-44) in the reply filed on 5/10/2004 and 8/16/2004):

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- a. For a *single specific* species of hydrophobic component, applicant has elected the terpolymer of dimethylaminoethyl methacrylate (DMAEMA), butyl methacrylate (BMA), and styrene benzaldehyde, which is described in Example 2 and illustrated in Figures 4 and 5.
 - b. For a *single specific* species of hydrophilic component, applicant has elected polyalkylene oxide (e.g., PEG).
 - c. For a *single specific* species of pH-sensitive linkage, applicant has elected acetal.
7. Claims 2-4, 8, 9, 13-17, 19, 33-36, and 38-44 are under consideration in this Office Action.

Priority

8. This instant application claims benefit to a provisional application of 60/174,893 filed 01/07/2000. This instant application is granted the benefit of priority for 60/174,893 under 35 U.S.C 119(e).

Maintained Rejection(s)

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
10. Claims 2-4, 8-10, 13-15, 19, and 33-35 are rejected under 35 U.S.C. 102(e) as being anticipated by Choi et al. (US Patent 6,210,717 B1).

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11. Claims 2-4, 8-10, 13-15, 19, and 33-35 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Choi et al. (US Patent 6,210,717 B1).

Withdrawn Objection(s) and /or Rejection(s)

12. The rejections of claims 2-4, 8-10, 13-16, 19, and 33-36 under 35 USC 102(e) as being anticipated by Heller et al. (US Patent 5,939,453) has been withdrawn in light of applicant's arguments, see pg. 11, lines 11-15, filed 10/19/2005.

Response to Arguments

13. Applicant's argument directed to the rejection under 35 USC 102(e) as being anticipated by Choi et al. (US Patent 6,210,717 B1) for claims 2-4, 8-10, 13-15, 19, and 33-35 was considered but they are not persuasive for the following reasons.

Choi et al. discloses a composition for delivering a selected nucleic acid and various kinds of ligands into a targeted host cell (see e.g. Abstract; col. 2, lines 29-55; col. 3, lines 12-34; col. 3, lines 54-63). The composition is a copolymer transport molecule that is comprised of a hydrophilic portion, a hydrophobic portion, and a functional moiety (refers to the claimed agent) coupled to the hydrophilic portion (see e.g. col. 2, lines 29-55; col. 3, lines 12-26; col. 4, lines 60-62). The hydrophilic portion and hydrophobic portion are linked through as amide bond or a graft copolymer comprising a hydrophobic polyester portion and a hydrophilic cation portion wherein the hydrophilic cation include polymer such as poly(L-serine ester) and poly(D-serine ester) (refers to the claimed pH-sensitive linkage)(see e.g. col. 2, lines 29-55; col. 6, lines 45-57). The functional moiety includes ligand, and nucleic acid (see e.g. col. 3, lines 12-26). Thus the composition of Choi et al. anticipates the presently claimed composition.

Additionally, the limitation that the pH-sensitive linkage is stable at a pH between 6.8 and 8 and hydrolyzed at a pH less than 6.5 to release the hydrophobic component is a functional limitation or a property of the claimed pH-sensitive linkage and it is presumed to be inherent. See MPEP § 2112.01. MPEP § 2112.01 states that:

II. >< COMPOSITION CLAIMS — IF THE COMPOSITION IS PHYSICALLY THE SAME, IT MUST HAVE THE SAME PROPERTIES
"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

The polymer linkage of Choi et al. is the same as the claimed pH-sensitive linkage of claim 8, i.e. an ester bond. Thus, the claimed functional limitation of the pH-sensitive linkage is inherent to the peptide linkage Choi et al. The limitation that the hydrophobic component is membrane-disruptive and allows enhanced transport through a cellular membrane are a functional limitation or a property of the claimed hydrophobic conjugate and it is presumed to be inherent since the copolymer of Choi et al. is the same as the claimed hydrophobic component of claims 4 and 35.

Applicant argues that the reference of Choi et al. does not anticipate the presently claimed invention because the '*Choi reference fails describe a copolymer having a hydrophobic portion covalently coupled to a hydrophilic portion through an ester bond*'. Thus, the reference of Choi et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Choi et al. do anticipate the composition of the instant claims. It is the examiner position is that the reference of Choi et al. do suggest the use of an ester group to link a polyester (hydrophobic) block or segment to a polycation (hydrophilic) block or segment to provide either a diblock or graft copolymer having polyester linked to polycation through an ester group. Choi et al. disclose a polyester-polycation block or graft copolymer comprising a hydrophilic polycation segment (ref. #14 of fig. 1) and a hydrophobic polyester segment (ref. #16 of fig. 1), i.e. the hydrophilic polycation segment is link to the hydrophobic polyester segment (col. 6, lines 40-43; fig. 1) and the linkage is ester bond (col. 6, lines 15-17 and 52-54). Additionally, Choi et al. also disclose an ester linkage between the hydrophilic polycation segment and the hydrophobic polyester segment by example (col. 8, lines 32-44). Therefore, the teachings of Choi et al. do anticipate the composition of the instant claims, and the rejection is maintained.

14. Applicant's argument directed to the rejection under 35 USC 102(e) as being anticipated by Choi et al. (US Patent 6,210,717 B1) for claims 2-4, 8-10, 13-15, 19, and 33-35 was considered but they are not persuasive for the following reasons.

Choi et al. discloses a composition for delivering a selected nucleic acid and various kinds of ligands into a targeted host cell (see e.g. Abstract; col. 2, lines 29-55; col. 3, lines 12-34; col. 3, lines 54-63). The composition is a copolymer transport molecule that is comprised of a hydrophilic portion, a hydrophobic portion, and a functional moiety (refers to the claimed agent) coupled to the hydrophilic portion (see e.g. col. 2, lines 29-55; col. 3, lines 12-26; col. 4, lines 60-62). The

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hydrophilic portion and hydrophobic portion are linked through as amide bond or a graft copolymer comprising a hydrophobic polyester portion and a hydrophilic cation portion wherein the hydrophilic cation include polymer such as poly(L-serine ester) and poly(D-serine ester) (refers to the claimed pH-sensitive linkage) (see e.g. col. 2, lines 29-55). The functional moiety includes ligand, and nucleic acid (see e.g. col. 3, lines 12-26). Thus the composition of Choi et al. anticipates the presently claimed composition.

*Alternatively, the claimed invention further differs from the prior art teachings only by the recitations of a) "the pH-sensitive linkage is stable at a pH between 6.8 and 8 and hydrolyzed at a pH less than 6.5 to release the hydrophobic component", i.e. the functional limitation of the pH-sensitive linkage, and b) "the hydrophobic component is membrane-disruptive and allows enhanced transport through a membrane only when released from the hydrophilic conjugate", i.e. the functional limitation of the hydrophobic component. The claimed invention appears to be the same or obvious variations of the reference teachings, absent a showing of unobvious differences. The structural features of the composition of Choi et al. are the same as the structural features of the claimed composition, which are a hydrophobic component and a hydrophilic component that are linked by a pH-sensitive linkage. The office does not have the facilities and resources to provide the factual evidence needed in order to determine and/or compare the specific activities of the instant versus the reference pH-sensitive linkage and hydrophobic component wherein the ability of the pH-sensitive linkage is stable at a pH between 6.8 and 8 and hydrolyzed at a pH less than 6.5 to release the hydrophobic component and the ability of the hydrophobic component to be membrane-disruptive and allows enhanced transport through a cellular membrane only when released from the hydrophilic conjugate. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed composition is different from the one taught by prior art and to establish the patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ2d 1922 (PTO Bd. Pat. App. & Int. 1989). See also MPEP 2112.01.*

Applicant alleges that the reference of Choi et al. does not anticipates the presently claimed invention because the '*Choi reference fails describe a copolymer having a hydrophobic portion covalently coupled to a hydrophilic portion through an ester bond*', hence the polymer of Choi et al. do not include a pH-sensitive linkage. Thus, the reference of Choi et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the teachings of Choi et al. do anticipate the composition of the instant claims. It is the examiner position is that the reference of Choi et al. do suggest the use of an ester group to link a polyester (hydrophobic) block or segment to a polycation (hydrophilic) block or segment to provide either a diblock or graft copolymer having polyester linked to polycation through an ester group and thus include a pH-sensitive linkage. Choi et al. disclose a polyester-polycation block or graft copolymer comprising a hydrophilic polycation segment (ref. #14 of fig. 1) and a hydrophobic polyester segment (ref. #16 of fig. 1), i.e. the hydrophilic polycation segment is link to the hydrophobic polyester segment (col. 6, lines 40-43; fig. 1) and the linkage is ester bond (col. 6, lines 15-17 and 52-54). Additionally, Choi et

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al. also disclose an ester linkage between the hydrophilic polycation segment and the hydrophobic polyester segment by example (col. 8, lines 32-44). Therefore, the teachings of Choi et al. do anticipate the composition of the instant claims, and the rejection is maintained.

Allowable Subject Matter

15. Claim 36 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter of claims 38-44:

The cited prior arts do not teach or fairly suggest the instant claimed composition of claims 38-44 comprising the combination of a hydrophobic synthetic vinyl-type polymer, a plurality of pendant hydrophilic polyalkylene oxide, and a plurality of pH-sensitive linkages.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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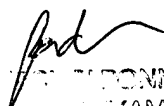
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
December 14, 2005


MY-CHAU T. TRAN
EXAMINER